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When should Open Surgery be the Initial Option for Critical Limb Ischaemia?☆

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Abstract *Objectives:* The treatment paradigm for patients with critical limb ischaemia (CLI) has changed over the past decade with an increase in endovascular interventions. Accompanying this shift has been a fundamental question as to whether open surgery or endovascular therapy represents the optimal treatment for CLI.
Design: Review.
Methods: A review of open versus endovascular surgery was performed. The supporting arguments by respective clinicians of both an 'open first' and an 'endo first' approach are summarised, followed by the available evidence in the literature for each. A summary of an informal survey of endovascular surgeons regarding five indications for an 'open first' approach to CLI are reviewed. Present and future clinical tools and research for providing a more objective decision for intervention in CLI are then summarised.
Results: Supporters of either an 'open first' or 'endo first' approach make claims which are not entirely supported by the current level 1 evidence. Five conditions which endovascular surgeons agree that patients with CLI should be treated primarily by open revascularisation include common femoral artery pathology; arterial occlusions caused by extrinsic compression pathologies; extensive foot gangrene/sepsis; young patients and those requiring dependent-free soft tissue reconstructions where durability is paramount; and infragenicular popliteal and proximal tibial occlusion with single, distal tibial target vessel. Clinical scoring systems and mathematical modelling of lower extremity disease assist in making a prospective intervention decision.
Conclusion: The treatment of CLI has changed and continued clinical and research work is focussed on which intervention is more effective. While more attempts at endovascular treatment are made, there remain specific indications for open surgical treatment of CLI. As more work is done towards determining optimal intervention choices on a patient-specific basis, clearer indications for either intervention will emerge.

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Introduction

In the past 10 years, there has been a dramatic increase in the total number of procedures for critical limb ischaemia (CLI), with most of that increase occurring in those patients undergoing endovascular procedures.[1] Meanwhile, the number of open surgical procedures has been reported either to have remained stable or diminished over the same time frame. Throughout this paradigm shift in the treatment of CLI, the indications for the initial application of either endovascular or open revascularisation remain controversial.

To provide some governing principles, the Trans-Atlantic Intersociety Consensus (TASC) II consensus document applied clinical results to identify the location and types of lower extremity lesions best treated by endovascular or open approaches.[2] These recommendations, however, only provided strong evidence for those patients with either the mildest or most severe disease patterns. Most patients 'in between' were still left to the physician's preference. The lower morbidity and lack of contraindications to endovascular interventions left many vascular specialists and institutions advocating an initial endovascular approach for all patients.

Now, nearly a decade since the shift from open surgery to endovascular treatment of CLI, there remains controversy regarding the optimal treatment approach to this disease process. While CLI is the subject of numerous opinions and lectures, level 1 evidence supporting either approach is lacking.[3] In this review, the current arguments for both 'open first' and 'endo first' approaches to CLI are summarised, followed by the most current published evidence supporting each approach. Specific parameters for 'open first' approaches to CLI, obtained from informal surveys of endovascular surgeons who routinely practice 'endo first' treatments, are summarised. In conclusion, current and future work directed at objectively determining the best first-line treatment for CLI is reviewed.

Arguments for 'open first' revascularisation approach

Those who argue for an 'open first' approach emphasise the durability of the approach, shorter healing times for tissue loss and similar morbidity to endovascular therapy when 'minimally invasive' open approaches are used. Open procedures, specifically autogenous vein bypasses, have been observed to have higher patency than endovascular procedures at similar time points. The application of minimally invasive techniques, such as endoscopic vein harvest and minimal incision *in situ* bypasses, may modify open procedures so that they are no more invasive than endovascular procedures. While many emphasise that there is a more complete revascularisation with open surgery and a greater increase in total blood flow, this premise must be confirmed by more objective evidence and must be the subject of further investigation. The financial impact of more durable open procedures over repeated endovascular procedures upon the health-care system and the relative economic benefit to the treating physician of multiple endovascular procedures have not been reported or calculated. The overall impact to the cost of health care, however, has identified the dramatic increase in the number of procedures in patients with CLI as one of the causes of increases in health-care costs over the past decade.

Arguments for 'endo first' revascularisation approach

Those who argue for an 'endo first' approach make the point that there is better patient acceptance, a lower initial morbidity and mortality, fewer wound complications and a more rapid return to normal activities. The perception of 'open first' surgeons that endovascular procedures may not provide the same volume of pulsatile flow as open procedures is offset by the observation that there may not be as much blood flow increase with endovascular procedures, but it is often adequate to treat most CLI symptoms despite a shorter patency of intervention. Many of the patients offered an 'endo first' approach have previously had harvesting of optimal conduits, including saphenous vein and radial arteries, for cardiac or other procedures and therefore have inferior open options. In addition, often not mentioned, is the better reimbursement for endovascular procedures per hour worked than for open surgery.

The 'endo first' approach is also often based on the limited life expectancy of many of these patients, who have co-morbidities such as diabetes or renal failure. The decreased patency of interventions superimposed upon a severely decreased life expectancy underlies the belief that there is no adverse consequence to an 'endo first' approach in all patients. Furthermore, they propose the position that an endovascular approach still allows for open surgery for those who fail percutaneous intervention and that the subsequent open procedure will not be modified by preceding endovascular attempts.

Evidence for 'open first' revascularisation approach

There are very few prospective, randomised controlled trials (RCTs) that directly compare endovascular procedures to open procedures in comparable patients with comparable disease locations. The primary study that carried out this comparison for infrainguinal disease was the Bypass versus Angioplasty for Severe Ischaemia of the Leg (BASIL) trial.[4] The study examined the primary outcome of amputation-free survival and secondary outcomes including mortality, morbidity, re-intervention, quality-of-life and cost. In support of an 'open first' approach, the subgroup analysis in the study found that surgery was the best option for patients with acceptable surgical risk and adequate vein conduit available. Those patients treated with open surgery who were living for 2 years or more after their intervention had a significantly lower risk of amputation, death or both combined. There is also unpublished data from Neville et al. which examined parameters of wound healing, time to complete wound healing and percentage of complete wound healing following open and endovascular interventions. They found that open surgery resulted in a significantly higher degree of complete wound healing with a trend towards shorter time to heal when compared with endovascular

interventions. Several studies have examined the patency of open infrainguinal surgical revascularisation. Data extrapolated from the PREVENT III trial considering the effect of pre-treatment of vein grafts on intimal hyperplasia revealed 1-year primary patency, primary assisted patency and secondary patency of 60.5%, 76.7% and 80.1%, respectively.[5] While there are no corollary, prospectively designed studies considering patency of infrapopliteal endovascular interventions, a study of 176 consecutive infrainguinal endovascular interventions for CLI revealed a 1-year primary patency rate of 53%.[6]

Evidence for 'endo first' revascularisation approach

The previously mentioned BASIL trial provided significant evidence interpreted as favourable to support an 'endo first' approach. They found no difference in the primary outcome of amputation-free survival between open and endovascular-first treatments. Open surgery was associated with a significantly higher morbidity in the form of wound infections and myocardial infarctions, a longer hospitalisation and a higher initial cost. The higher initial cost of surgery was equal to endovascular treatment at 3 years resulting from a higher failure rate (20% endo vs. 3% open) requiring a higher rate of re-interventions (28% endo vs. 17% open). This study, however, did not evaluate the effect of these repeated procedures or outcomes longer than 5 years post-intervention. In spite of these shortcomings, this study suggests that there is clinical equipoise between an 'endo first' approach and an 'open first' approach. An RCT comparing open versus endovascular treatment of symptomatic iliac disease showed no difference in patency or limb salvage at 4-year follow-up.[7] While some limitations to this study were noted, a relatively lower morbidity and mortality rate for endovascular intervention supports an 'endo first' approach for this disease location.

Parameters for 'open first' revascularisation approach

In 2009, at the Society for Vascular Surgery annual meeting, this clinical equipoise was addressed in the form of a debate, conducted by two vascular surgeons who had access to and training in both endovascular and open techniques. Each was a strong advocate for either an initial endovascular or open approach to treating CLI. At the conclusion of the debate, over 700 vascular specialists who were present were asked to vote on the evidence presented during the debate and whether they favoured an open or endovascular initial approach as initial therapy of infrainguinal arterial occlusive disease of TASC D complexity. The audience overwhelmingly voted in support of the open approach, while concurrently reporting more frequently using an endovascular approach in their practices. Why did they believe that the evidence supported an initial open approach and yet use an endovascular approach for their patients with TASC D disease? Was it the professional reimbursement that favours the endovascular approach, or was it that these lesions are much less common than TASC A, B or C lesions in their practices?

To answer questions about the motivation and practice of using the 'open first' approach in selected patients with TASC D disease, we interviewed several committed endovascular surgeons and asked them the following question: As an 'endo first' vascular surgeon, what are the situations in which you would favour an ''open first'' approach? These surgeons came up with five situations in which an open approach should be the initial therapy, despite their common application of initial endovascular treatment.

1. *Anatomy*: These vascular surgeons felt that certain pathology, when located in specific anatomic locations, made the open approach more attractive. This included patients with disease primarily of the common femoral artery (Fig. 1). In common femoral artery disease, the atherosclerosis often extends above the inguinal ligament and is difficult to treat with endovascular procedures. Commonly, the calibre of the femoral is larger than most atherectomy devices, the plaque burden is great and the vessel is often calcified, making it particularly challenging for endovascular procedures. In addition, the surgical procedure is relatively low risk and simple, with a small subcutaneous incision and a rapid recovery.
2. *Pathology*: Certain disease of the infrapopliteal vessels is not conducive to angioplasty/stenting and includes extrinsic compression from popliteal entrapment, adventitial cystic disease and exostoses associated with arterial compression and occlusion (Fig. 2). In each of these circumstances, an dendovascular procedure does not eliminate the cause of the stenosis, and when there is extrinsic compression, the underlying cause of the

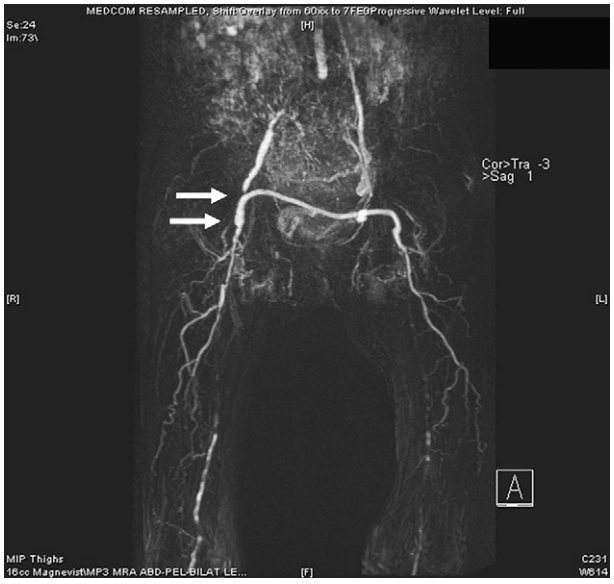

Figure 1 Common femoral artery disease represents a location agreed to be optimally treated with open revascularization due to the ease of accessibility, as well as external compression from the inguinal ligament resulting in failure of endovascular prostheses. Here progression of common femoral artery disease on the right, donor leg is threatening this femoral-femoral bypass.

stenosis or occlusion cannot be corrected with an endovascular procedure.

3. *Physiology*: When patients have extensive foot sepsis or gangrene, open procedures deliver more pulsatile flow to the limb, and therefore should be used in these clinical settings (Fig. 3). Until a system is devised to determine the volume of blood flow needed to resolve particular clinical problems, the maximum blood flow should be delivered in settings where there is a high risk of limb loss without a marked increase in blood flow. This clinical scenario is particularly relevant to emergency situations with extensive foot gangrene and/or infection. Endovascular approaches run the risk of providing increased but inadequate flow to the foot, which is not discovered to be inadequate until more tissue is lost, often mandating a higher level of amputation.
4. *Durability*: Patients who are young and need limb-salvage procedures for critical limb ischaemia require a durable procedure. Endovascular procedures have considerably shorter durability in most situations and therefore need repeated procedures for restenosis. In addition, some patients need a long-term durable procedure for maintenance of a free flap or a distal procedure that is dependent on the patency of the proximal procedure (Fig. 4). In this case, an open procedure is preferable. Endovascular procedures in young patients may relegate the patient to repeated, lifelong procedures with repeated hospitalisations, thrombolysis and eventual failure of the revascularisation procedure.
5. *Limited distal targets*: Occlusion of the infrageniculate popliteal artery as well as the origins of all three tibial arteries presents a challenging endovascular revascularisation primarily due to limited patency and high failure rates (Fig. 5). Every vascular surgeon has encountered a situation where a patient with an excellent conduit and a single distal target vessel in the ankle or foot loses that target during repeated endovascular procedures, due to embolism or thrombosis of the target vessel. When a patient has a good conduit and a good, but single target, this is an optimal situation for an open procedure before that target is lost.

Current and future approaches to treatment choice

While most dialogue regarding the choice between open and endovascular treatments of CLI has been based on the evidence produced from clinical trials and series, the logical solution would involve the creation of a prospective tool to determine which intervention would result in the greatest benefit. Taylor et al. proposed a scoring system, known as the Lower Extremity Grading System (LEGS) score, to guide initial treatment of those with CLI.[8] This system incorporates several clinical variables such as disease location, symptoms, functional status, co-morbidities and technical factors to arrive at a composite index which directs treatment to either open surgery, endovascular treatment or primary amputation. They found that the application of this scoring system predicted the actual or offered clinical treatment 90% of the time. In a more engineering-based approach to objective decision making regarding optimal intervention, the authors of this article proposed and presented the concept of mathematical

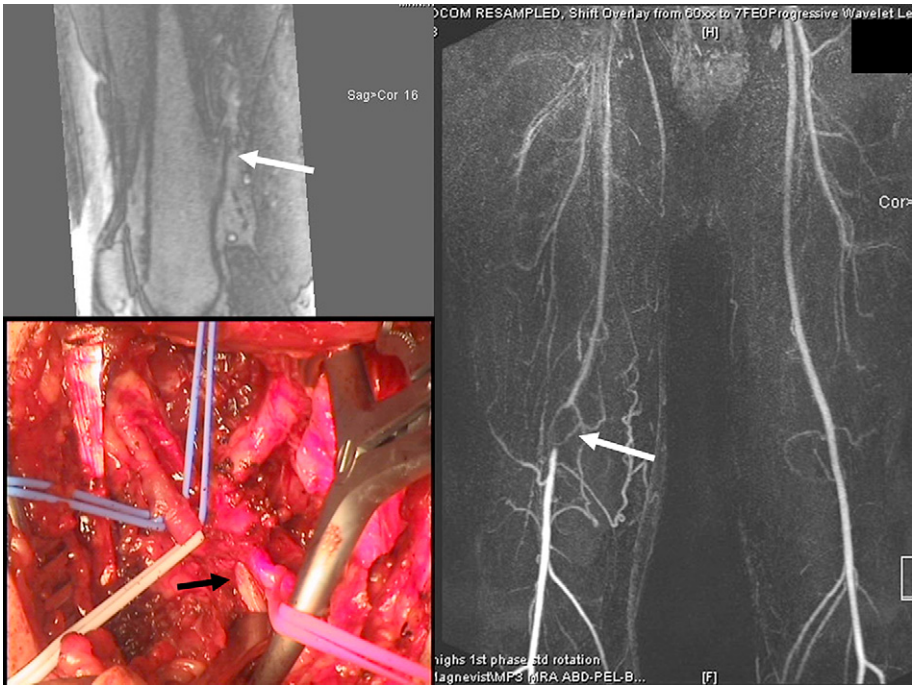

Figure 2 Open surgical treatment of certain pathologies, such as occlusion of the superficial femoral artery from bony exostoses from the femur shown here, appears to be preferred over endovascular techniques. Other such pathologies include popliteal entrapment and adventitial cystic disease.

Figure 3 Severe limb gangrene and/or sepsis involving the forefoot (left) or the lower leg (right) is more often treated with open surgical revascularization than endovascular therapy.

modelling of the femoropopliteal circulation with interventions as a method of preoperatively predicting whether open bypass or angioplasty/stent would result in a higher distal perfusion pressure.[9] With work towards expanding this model to include the entire lower extremity circulation, multi-level disease could be modelled along with several intervention options including open, endovascular or a combination of both. Further work must be done as well trying to quantify the actual changes in tissue perfusion and distal blood flow after either open or endovascular treatment and compare the two. In a field as studied as this, it seems peculiar that concepts such as quantifiable patterns of tissue perfusion after certain anatomic revascularisations and measurable levels of tissue blood perfusion needed to heal wounds or ameliorate rest pain remain unknown. Clearly, this information would assist in clarifying the debate.

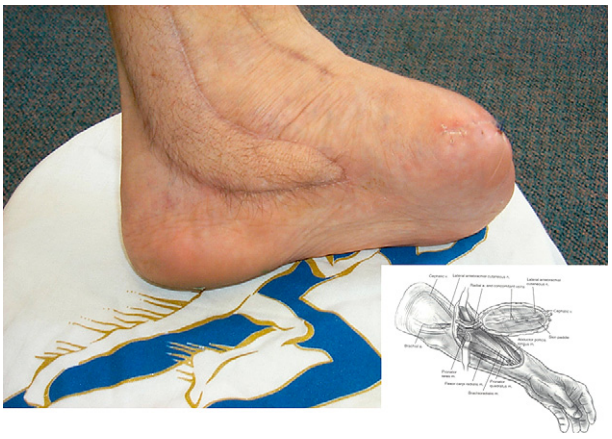

Figure 4 Due to improved patency associated with autogenous vein bypasses, these are often the optimal choice over endovascular techniques for patients requiring free-tissue coverage. These flaps have greater viability when their blood flow is dependant on native circulation or an autogenous conduit.

Figure 5 Severe occlusive disease involving occlusions of the infrageniculate popliteal artery and the proximal segments of the tibial arteries pose a technical challenge for endovascular recanalization. With patients who have single distal targets and CLI, an autogenous vein distal bypass often provides the more durable reconstruction. These patients, with percutaneous revascularization, are often at risk for embolic/thrombotic occlusion of the reconstituted distal tibial artery.

Conclusion

In conclusion, CLI has been treated primarily with open surgical bypass prior to the increase of endovascular treatment nearly 1 decade ago. The debate continues regarding the optimal initial intervention with practitioners applying either an 'open first' or 'endo first' strategy. There are specific arguments lavied by each side supporting their approach. While copious retrospective, observational clinical data exist examining this topic, there are very few prospective RCTs supporting either approach exclusively. A survey of endovascular surgeons with a preference for an 'endo first' approach revealed five parameters which would guide them to apply open surgery as the initial treatment for CLI. To further guide decision making, prospective tools have been developed and are the basis of further research work. Once the ability to quantify limb perfusion in the setting of CLI is available, more information regarding the effectiveness of open versus endovascular treatment will be realised and a refined approach to the treatment of CLI can be constructed.

Conflict of Interest/Funding

None.

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